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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,508	01/08/2002	Thomas O. Murdock	ARC 2452D1	7206

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ALZA CORPORATION
P O BOX 7210
INTELLECTUAL PROPERTY DEPARTMENT
MOUNTAIN VIEW, CA 940397210

EXAMINER	
JOLLEY, KIRSTEN	
ART UNIT	**PAPER NUMBER**
1762	

DATE MAILED: 12/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/042,508	MURDOCK, THOMAS O.	
	Examiner	Art Unit	
	Kirsten C Jolley	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 30-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 30-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/9/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments/Amendments

1. Applicant's arguments filed August 30, 2004, with respect to Haak et al. have been fully considered and are persuasive. The 35 USC 103(a) rejections over Haak et al. have been withdrawn. Haak et al. does not teach or suggest applying solvent and dissolved beneficial agent to a surface of hydrophilic polymer filtration membrane and then removing the solvent from the filtration membrane *to form a hydratable agent-containing matrix*. However, a new ground(s) of rejection is made in view of the newly-cited reference of Higo et al. (US 5,908,400). The remainder of Applicant's arguments have been considered as well, but are moot in view of the new grounds of rejection.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-2, 6-7, and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Higo et al. (US 5,908,400).

Higo et al. discloses a method of forming an anhydrous reservoir layer of an electrode assembly in an electrically powered electrotransport agent delivery device, the reservoir layer

having a matrix and being adapted to be placed in agent-transmitting relation with a body surface and an electrode in electrical contact with a power and the reservoir layer, comprising the steps of: dissolving a beneficial agent in a solvent, and applying the solvent and dissolved beneficial agent to a surface of a hydrophilic polymer filtration membrane (col. 14, lines 44-49); removing the solvent from the filtration membrane forming a hydratable agent-containing filtration membrane 8 (col. 15, lines 51-62); and disposing the hydratable agent-containing matrix 8 within the electrode assembly (col. 6, line 66 to col. 7, line 4). It is known that the drug holder or retainer layer of Higo et al. is a filtration membrane because Higo et al. teaches that the drug holder or retainer layer has a porous or capillary structure, having pore sizes similar to those taught in the specification, and made of similar polymeric materials as those taught in the specification, including the use of hydrophilic polymers (col. 9, line 59 to col. 10, line 34). Additionally, Higo et al. teaches that the drug layer is present in a dry condition and is hydrated when brought into contact with the hydrophilic, polymeric gel layer so that the drug in the drug layer is dissolved, therefore the drug layer also is a hydratable matrix (col. 7, lines 38-41).

As to claim 2, Higo et al. teaches dissolving the drug/agent in water, which is an aqueous based solvent (col. 14, lines 44-45).

As to claim 6, Higo et al. teaches that the drug retainer layer 8, or filtration membrane, may be made of polysulfone in col. 10, line 7.

As to claim 32, it is noted that Higo et al.'s hydrophilic, polymeric gel layer is a "hydrating material" and is located between the electrode and the hydratable agent-containing matrix.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 3-5, 8-11, 30-31, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Higo et al.

Higo et al. is applied for the reasons discussed above in section 3.

As to claims 3-4, Higo et al. lacks a teaching of using ethanol or isopropanol as the solvent for dissolving the drug in the porous drug retainer layer. It is well known in the art that ethanol and isopropanol are two aqueous solvents compatible with the body, in addition to water. It would have been obvious for one having ordinary skill in the art to have substituted, or added, another aqueous solvent other than water that is also compatible with the body, such as ethanol or isopropanol, with the expectation of similar and successful results.

As to claim 5, Higo et al. broadly teaches using "porous polysulfones" as the material for the drug retainer layer, however does not provide specific polysulfone materials. It would have been obvious for one skilled in the art to have selected a known porous polysulfone material that is generally low in adsorption of drugs, such as polyether sulfone, for use as the drug retainer material in Higo et al.'s process with the expectation of successful results since Higo et al. generally discloses use of polysulfones and is not limiting.

As to claims 8-11, Higo et al. discloses drying the membrane/drug retainer layer so that the drug-retaining layer is "well dried" (col. 15, lines 51-58). It would have been obvious for

one skilled in the art to have used conventional drying means, such as a forced air oven, vacuum drying oven, desiccator, or lyophilization, in order to dry the drug-retaining layer since Higo et al. is silent and not limiting with respect to specific drying means.

As to claims 30-31 and 33, Higo et al. is silent with respect to the amount of residual moisture content in the hydratable drug-retaining layer. However, Higo et al. states that the layer should be "well dried," and teaches use of a drying agent to ensure the dryness during packaging/storage. Therefore, Higo et al. would have clearly suggested to one skilled in the art to have completely dried the drug-retaining layer, for example to less than 5% or 1%, in order to achieve optimal results. Further, as to claim 33, Higo et al. teaches that the drug-retaining layer has a thickness in the range of 1-500 μm, or 0.04-20 mils. Overlapping ranges are *prima facie* evidence of obviousness. It would have been obvious to one having ordinary skill in the art to have selected the portion of Higo et al.'s thickness range that corresponds to the claimed range. *In re Malagari*, 184 USPQ 549 (CCPA 1974).

Conclusion

6. Applicant's amendments and submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on August 9, 2004 necessitated/prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kirsten C Jolley whose telephone number is 571-272-1421. The examiner can normally be reached on Monday to Thursday and every other Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P Beck can be reached on 571-272-1415. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kirsten C Jolley
Primary Examiner
Art Unit 1762

kcj